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| 10/604,022 | 06/23/2003 | Jonathan McKinno Collins | 1700.129 | 1021 |
| 21176 | 7590 | 11/21/2005 | EXAMINER | |
| SUMMA, ALLAN & ADDITON, P.A. 11610 NORTH COMMUNITY HOUSE ROAD SUITE 200 CHARLOTTE, NC 28277 | | | CORDERO GARCIA, MARCELA M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1654 | |

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/604,022

Applicant(s)

COLLINS ET AL.

Examiner

Marcela M. Cordero Garcia

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 62-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 62-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 1005.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the reply received on October 24, 2005.

Claims 1-12 and new claims 62-82 are pending in the application.

Any rejection from the previous office action, which is not restated here, is withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-12 and 62-82 are presented for examination on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3-6, 8-9, 11-12, 62, 64-66, 68-73, 75-76, 78-79 and 81-82 are rejected under 35 U.S.C. 102(a) as being anticipated by Porcheddu et al. (Eur. J. Org. Chem., 2003).

Porcheddu et al. teach a process for the solid phase synthesis of peptides, which comprises:

(a) deprotecting a first amino acid linked to a solid phase resin by removing protective first chemical groups;

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(b) activating chemical groups on a second amino acid to prepare the second amino acid for coupling with the first amino acid;

(c) coupling the activated second amino acid to the deprotected first amino acid to form a peptide from the first and second amino acids; and

(d) accelerating at least the deprotecting and coupling steps by applying microwave energy during the deprotecting and coupling steps. Please note that the instantly claimed functional effects (e.g., preventing undesired degradation by limiting heat accumulation) would be inherent to the method taught by Porcheddu et al. (See, e.g., abstract; page 907, column 2, lines 14-17; page 910, columns 1-2).

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 and 62-82 are rejected under 35 U.S.C. 103(a) as being anticipated by Porcheddu et al. (Eur. J. Org. Chem., 2003) in view of Stadler et al. (Eur. J. Org. Chem., 2001).

Porcheddu et al. beneficially teach a process for the solid phase synthesis of peptides, which comprises:

- (a) deprotecting a first amino acid linked to a solid phase resin by removing protective first chemical groups;
- (b) activating chemical groups on a second amino acid to prepare the second amino acid for coupling with the first amino acid;
- (c) coupling the activated second amino acid to the deprotected first amino acid to form a peptide from the first and second amino acids; and
- (d) accelerating at least the deprotecting and coupling steps by applying microwave energy during the deprotecting and coupling steps. (See, e.g., abstract; page 907, column 2, lines 14-17; page 910, columns 1-2).

Porcheddu et al. do not expressly teach the instantly claimed method further comprising cleaving the peptide from the solid phase resin while applying microwave energy to accelerate the cleaving step or further comprising deprotecting side chains on the amino acids of the peptide under microwave irradiation.

Stadler et al. (Eur. J. Org. Chem., 2001) beneficially teach cleaving a peptide analog from the solid phase resin while applying microwave energy to accelerate the cleaving step. (See, e.g., page 922, column 2, lines 32-41; page 923, column 1 and 2 and Scheme 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust particular conventional working conditions within such solid phase peptide synthesis process (e.g., utilizing microwave energy to accelerate the cleavage of the peptide from the solid phase resin, as beneficially taught by Stadler et al. (see above) and/or expressly deprotecting a side chain of a peptide using microwave irradiation) based upon the overall beneficial teachings provided by Porcheddu et al. These types of adjustments are deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan. Please note that the instantly claimed functional effects (e.g., preventing undesired degradation by limiting heat accumulation) would be intrinsic to the method taught by Porcheddu et al.

Thus, the invention as a whole is prima facie obvious over the reference, especially in the absence of evidence to the contrary.

Claims 1-12 and 62-82 are rejected under 35 U.S.C. 103(a) as being anticipated by Daga et al. in view of Santagada et al. (Tetrahedron Letters, 2001, citation 4 in the IDS of November 8, 2004) and in view of Stadler et al. (Eur. J. Org. Chem., 2001).

Daga et al. beneficially teach a process for the solid phase synthesis of peptides, which comprises:

(a) deprotecting a first amino acid linked to a solid phase resin by removing protective first chemical groups;

(d) accelerating at least the deprotecting cycle step by applying microwave energy during the deprotecting step. (See, e.g., page 5191, lines 14-17; page 5193, column 1, lines 3-31 and column 2, lines 10-15 and Table 1).

Daga et al. do not expressly teach steps (b) and (c), nor do they expressly teach the instantly claimed method further comprising cleaving the peptide from the solid phase resin while applying microwave energy to accelerate the cleaving step or further comprising deprotecting side chains on the amino acids of the peptide under microwave irradiation.

Santagada et al. beneficially teach a process for the synthesis of peptides, which comprises:

(b) activating chemical groups on a second amino acid to prepare the second amino acid for coupling with the first amino acid;

(c) coupling the activated second amino acid to the deprotected first amino acid to form a peptide from the first and second amino acids;

(d) accelerating at least the coupling step by applying microwave energy during the coupling step (see, e.g., abstract and Table 1).

Stadler et al. (Eur. J. Org. Chem., 2001) beneficially teach cleaving a peptide analog from the solid phase resin while applying microwave energy to accelerate the cleaving step. (See, e.g., page 922, column 2, lines 32-41; page 923, column 1 and 2 and Scheme 2).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the microwave activation for both deprotecting

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and coupling during solid-phase peptide synthesis in order to accelerate the synthetic process since Daga et al. beneficially teach that their method for accelerating and yield improving deprotection using microwave irradiation has potential application in more complex synthesis on polymeric support (i.e., solid phase) and because Santagada et al. beneficially teach that their microwave irradiation method significantly reduces reaction times of dipeptide synthesis and is potentially applicable to solid phase peptide synthesis in general. Porcheddu et al. beneficially teach using a beaker with water to “proactively cool the vessel and its contents during application of microwave energy” and applying microwave energy for 1 minute the resting 1 minute, which reads upon “limiting the application of microwave energy to relatively short time intervals”. The adjustment of particular conventional working conditions (e.g., utilizing microwave energy to accelerate the cleavage of the peptide from the solid phase resin, as beneficially taught by Stadler et al. (see above) and/or expressly deprotecting a side chain of a peptide using microwave irradiation) is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan. Please note that the instantly claimed functional effects (e.g., preventing undesired degradation by limiting heat accumulation) would be intrinsic to the method taught by Daga et al.

Thus, the invention as a whole is prima facie obvious over the reference, especially in the absence of evidence to the contrary.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

No claim is allowed.

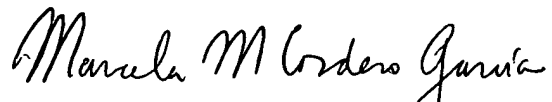
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Marcela M Cordero Garcia, Ph.D.
Patent Examiner
Art Unit 1654

MMCG 11/05



CHRISTOPHER R. TATE
PRIMARY EXAMINER